



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
PO Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,968	09/19/2000	Ping Yip	24736-2049	4499

24961 7590 08/12/2003

HELLER EHRLMAN WHITE & MCAULIFFE LLP
4350 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122-1246

EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

17

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/663,968	YIP, PING
	Examiner Channing S. Mahatan	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 May 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-45 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) A Declaration is filed under 35 U.S.C. § 119(e) (to a provisional application). See 37 CFR 1.121.

Attachments

1) Notice of References Cited in this Office Action

2) Notice of Draftsperson's Patent Drawing Review (PTO-940)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 Sheets

4) Notice of Allowance Summary (PTO-1447)

5) Notice of Informal Patent Application (PTO-152)

6) Other

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 16, filed 21 May 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-45.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-45 are rejected under 35 U.S.C. § 112, first paragraph, because the specification while being enabling for "removing putative peaks from the intermediate data set" and "generating a data set indicative of the mass of DNA fragments in the sample", does not reasonably provide enablement for the all uses of the putative peak to remove residual baseline effects (i.e. claims 1, 38, 40, and 45) and other means for "generating a data set". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following indicates particular pages and line numbers within the specification for which each of

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

SCOPE OF ENABLEMENT

Claims 1, 38, 40, 41, 45 and all claims dependent therefrom while being enabled for the “removing putative peaks from the intermediate data set” (i.e. Figure 2), does not reasonably provide enablement for all uses of the putative peak to remove residual baseline effects. A general summary of the disclosed method, system, and computer readable medium for identifying a biological sample is: 1) receiving a data set indicative of the mass of DNA fragments in the sample (addressed below); 2) denoising the data set to generate a denoised data set (page 7-8, beginning on line 21 to line 13, respectively); 3) correcting the baseline from the denoised data set and generating an intermediate data set (page 8, lines 14-21 of the Specification); 4) define putative peaks (page 17, lines 5-21); 5) remove putative peaks from the

residual baseline from the intermediate data set, thereby generating a corrected data set (page 18, lines 15-20); 7) locating a probable peak in the corrected data set; and 5) identify biological sample based on the probable peak (pages 19-20). It is acknowledged the specification does teach “using the putative peaks to remove residual baseline effects” (i.e. claim 1, line 9) as follows:

“To remove the residual baseline line effects, FIG. 22 shows that the putative peaks 218, 222, and 224 are removed from the baseline corrected signal... The peaks are removed and the remaining minima 247 located as shown in FIG. 23 with the minima 247 connected to create signal 245. (page 18, lines 4-20)

However, the use of the putative peaks (based upon peak height and area beneath peak) is limited to the putative peaks being removed from the baseline corrected signal (i.e. intermediate data set; claim 1, line 7) after which a peak free signal is generated and techniques to smooth or fit the peak free signal is applied to generate a residual baseline (page 18, lines 4-20). There is no further guidance as to use the putative peaks in any other way (i.e. adding the putative peaks to the baseline corrected signal).

Claim 1 (line 3), 38 (line 3), 41 (line 3), 45 (line 3), and all claims dependent therefrom while being enabled for the disclosed step of “generating a data set” indicative of the mass of DNA fragments in the sample (page 6-7, lines 10-25 and 1-20, respectively) fails to provide for other means for “generating a data set”. Applicants argue general techniques and conditions for “generating a data set” are provided in the specification and are known to the skilled artisan (i.e. mass spectrometer and chromatograph instruments), thus, would not require undue experimentation to “generate a data set” comprising data of the components in a biological sample as instantly claimed. Further, applicants point to the specification for the broad teaching

identification of the biological sample can be used, and a mass spectrometer is only one embodiment thereof" (page 7, lines 6-13). Applicant's arguments are found unpersuasive, further clarification by way of example is provided for below. It is noted applicants submit that the term components (i.e. in a biological sample) is a term understood by artisans in diverse disciplines and provides a definition of "an element forming a part of the whole" (Paper No. 16, filed 21 May 2003, page 28). Sehgal et al. (Isolation and Characterization of a Novel Gene from Human Glioblastoma Multiforme Tumor Tissue) describes the identification of a novel gene that is overexpressed in glioblastoma multiforme tissue as compared to normal brain tissue (Abstract) and generates an autoradiogram (Figure 1) and sequence (Figure 3) indicative of a "generated data set" of components of the biological sample. In view of Sehgal et al. and the "generated data set" therein, the applicants' original disclosure fails to provide for any indication that a generated autoradiogram or sequence data set, broadly encompassed by the instant claim language, can be utilized in the claimed invention. For example, the specification does not indicate steps for converting a generated sequence data set into peaks which can then be denoised, baseline corrected, define putative peaks, etc. No guidance, direction, or examples of the broadly encompassing "generated data set" are provided such that one of ordinary skill in the art would have known how to practice the claimed invention.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

Art Unit: 1631

Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *August 1, 2003*

Examiner Initials: *CMA*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
AC/1631